

§ 73.18

(iii) Where stored (e.g., building, room, and freezer),

(iv) When moved from storage and by whom and when returned to storage and by whom,

(v) The select agent used and purpose of use,

(vi) Records created under § 73.16 and 9 CFR 121.16 (Transfers),

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient, and

(viii) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release),

(2) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics,

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source,

(iii) The initial and current quantity amount (e.g., milligrams, milliliters, grams, etc.),

(iv) The toxin used and purpose of use, quantity, date(s) of the use and by whom,

(v) Where stored (e.g., building, room, and freezer),

(vi) When moved from storage and by whom and when returned to storage and by whom including quantity amount,

(vii) Records created under § 73.16 and 9 CFR part 121.16 (Transfers),

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient,

(ix) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release), and

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom,

(3) A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator,

(4) Information about all entries into areas containing select agents or toxins, including the name of the indi-

42 CFR Ch. I (10–1–11 Edition)

vidual, name of the escort (if applicable), and date and time of entry,

(5) Accurate, current records created under § 73.9 and 9 CFR part 121.9 (Responsible Official), § 73.11 and 9 CFR part 121.11 (Security), § 73.12 and 9 CFR part 121.12 (Biosafety), § 73.14 and 9 CFR part 121.14 (Incident response), and § 73.15 and 9 CFR part 121.15 (Training), and

(6) A written explanation of any discrepancies.

(b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate, have controlled access, and that their authenticity may be verified.

(c) All records created under this part must be maintained for three years and promptly produced upon request.

§ 73.18 Inspections.

(a) Without prior notification, the HHS Secretary, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, the HHS Secretary may inspect and evaluate the premises and records to ensure compliance with this part.

§ 73.19 Notification of theft, loss, or release.

(a) Upon discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported immediately by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information),

(ii) An estimate of the quantity lost or stolen,